REMARKS/ARGUMENTS

Upon entry of this amendment claims 1, 7-40, 76-79 and 82 will be pending in this application. Claims 2-6, 41-75 and 80-81 were previously canceled. Claims 1, 8-9, 13-15, 21, and 28-29 are currently amended. Amendments to claims 1 and 21 are described below. Amendments to claims 8-9, 13-15, and 28-29 are typographical in nature. No new matter has been added.

The Applicant thanks the Examiner for withdrawing the finality of the previous Office Action in light of Applicant's Request for Continued Examination and for entering Applicant's submission filed on May 27, 2008.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

In the Non-Final Office Action mailed July 1, 2008, the Examiner rejected claims 1, 7-40, 76-79 and 82 under 35 U.S.C. § 112, second paragraph as indefinite. Specifically, the Examiner states that the preambles of independent claims 1 and 21 recite methods for delivering permeant substances, but that no positive steps in this regard follow in the body of each claim. Applicants respectfully submit the amendments to the claims obviate the rejection.

The Applicant has amended claims 1 and 21 to incorporate a step of delivering said substances by placing a patch comprising the substance over one or more delivery openings. As one non-limiting example, this step finds support in paragraph 57 of the published application. Support for "one or more" delivery openings is found, in one non-limiting example, in paragraph 39. In light of the amendments, Applicants respectfully request the rejection under 35 U.S.C. § 112 second paragraph be withdrawn.

Claim Rejections - 35 U.S.C. § 103(a)

In the Non-Final Office Action mailed July 1, 2008, the Examiner rejected claims 1, 7-40, 76-79 and 82 under 35 U.S.C. § 103(a) as obvious over U.S. patent 6,022,316 to Eppstein (hereto referred to as "Eppstein"). The Examiner states that Eppstein teaches micropores formed to a depth of 40-180 microns. The Examiner acknowledges that Eppstein does not teach or suggest a range of 40-90 microns. However, the Examiner argues that one of ordinary skill in

the art would be able to arrive at the claimed range because methods for measuring pore depth, as evidenced by the present application, are "completely subjective."

Applicants respectfully traverse the rejection. First, Applicants respectfully submit that the methods of measuring pore depth as disclosed in the pending application are not "subjective." Prior to the present invention, methods for characterizing the depths of pores formed by microporation devices were unknown. The Applicants disclose reproducible scientific methodologies for determining pore depths. Examples of such methods include the use of a microscope and digital depth indicator (paragraphs 47-48), the use of tracer compounds and confocal fluorescent microscopy (paragraph 49), electrical impedance measurements (paragraph 50), and TEWL measurements (paragraphs 72-75). As one non-limiting example, the Applicants direct the Examiner to Example 1 in the published application (beginning at paragraph 78). Here the digital depth indicator method was used. The average depth for a set of 8 pores, wherein different operators measured the same set of pores, was found to be within 9 microns and had nearly identical standard deviations (paragraph 88). Therefore, Applicants respectfully submit that the disclosed methods of determining mean pore depth are not subjective.

Second, and more importantly, Applicants respectfully submit that the Examiner has not factually supported the *prima facie* conclusion of obviousness. Apart from addressing the methods used to measure pore depth, the Examiner has not given any reason that the claimed range, i.e., 40-90 microns, would have been obvious. Applicants are the first to disclose a relationship between the mean pore depth of an opening and the flux rate of a permeant. More specifically, the present specification teaches that a narrower range of 40-90 microns in the distribution of pore depths will allow for an acceptable flux rate of the permeant across the biological membrane (paragraphs 53). The methods of measuring pore depth as disclosed in the present application are necessary to evaluate that relationship between mean pore depth and the flux rate of a permeant, but they don't make the range itself obvious.

For at least the foregoing Applicants submit the rejection under 35 U.S.C. § 103(a) has been overcome and respectfully request that it be withdrawn.

CONCLUSION

The foregoing is submitted as a full and complete response to the Non-Final Office Action mailed July 1, 2008, and early and favorable consideration of the claims is requested. If the Examiner believes any informalities remain in the application that may be corrected by Examiner's amendment, or there are any other issues which can be resolved by telephone interview, a telephone call to the undersigned agent at (404) 572-2473 is respectfully solicited.

No further fees are believed to be due in connection with this response. However, the Commissioner is hereby authorized to charge any underpayment or credit any overpayment of fees to Deposit Account No. 11-0980.

Respectfully submitted,

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